

REMARKS

Claims 104-109 and 115-126 are pending in the application. Claims 127-135 are added. Claims 115 and 120-126 are amended. Claims 116-119 are canceled. Claims 104-109 are withdrawn. Applicants respectfully requests reconsideration in view of the above amendments and following remarks.

Support for new Claims 127-135 and amendments to the existing claims can be found in the specification, at least, on pages 47-49 of Applicants' Application. No new matter is added with the amendments or the addition of new claims.

I. CLAIMS 115 AND 117-123 ARE PATENTABLY DISTINGUISHABLE OVER HERMANN, *ET AL.*

The Office rejected Claims 115 and 117-123 under 35 U.S.C. § 102(b) as being anticipated by Hermann, *et al.*, U.S. Patent No. 5,599,309 ("the '309 patent"). This rejection is respectfully traversed.

The Office stated that "Hermann teaches all the claimed subject matter" and teaches the use of a guide wire.

The Office cites the subject matter of Hermann at Col. 11, lines 21-33 and 47-65 as anticipating Applicants' invention. These citations are directed to the use of a introducer catheter system 10. In particular, the introducer catheter system 10 includes an introducing catheter 12 and an obturator 14. Hermann at Col. 9, ll. 41-44; *see also* Herman Figs. 1-5. The introducer catheter 12 comprises a flexible sheath 16 and a homeostasis valve assembly 18. *Id.* at Col. 9, ll. 44-45. The obturator 18 comprises a flexible body portion 20 and an actuator handle 22. *Id.* at Col. 9, ll. 45-47. During use, the introducer catheter system is oriented such that the distal end of the system enters

the target artery. *Id.* at Col. 11, ll. 21-23. Once positioned, the obturator 14 is removed leaving the sheath 16. *Id.* at Col. 11, ll. 47-49.

Claims 117-119 are canceled and thus obviates this rejection with regard to these claims. Applicant respectfully requests the withdrawal of this rejection.

Unlike Hermann, Applicants' disclose "the use of *more than one* unique introducer *sheath device* 900." Applicants' application at 40, ll. 18-41, ll. 9 (emphases added). As such, Applicants' amended claim 115 provides "a method of repairing an aneurysm in a vessel using *at least two sheath devices*" See Applicants Amendments to the Claims (emphasis added). Hermann fails to disclose or suggest a method of using at least two introducer catheter *systems* 10 and/or at least two introducer *catheters* 12 in communication with one another. Hermann at Col. 2, ll. 50-52; Col. 11, ll. 21-23. Since Claims 120-123 depend from and contain all the limitations of Claim 115, Claims 120-123 also point out and distinctly claim that subject matter which Applicant regards as an embodiment of the invention in the same manner as Claim 115.

Thus, Applicants' invention is patentably distinguishable over Hermann. Applicants respectfully request the withdrawal of this rejection.

II. CLAIMS 116 AND 124-126 ARE PATENTABLY DISTINGUISHABLE OVER HERMANN, *ET AL.* IN VIEW OF GROSS.

The Office rejected Claims 116 and 124-126 under 35 U.S.C. § 103(a) as being unpatentable over Herman, *et al.* in view of Gross, U.S. Patent No. 5,407,434 ("the '434 patent"). This rejection is respectfully traversed.

The Office stated that "Hermann teaches all the claimed subject matter except for the self-sealing material being a 'gel-like' material." The Office further stated that Gross teaches "the use of gel to seal around instruments and to seal the passage completely when the instruments are removed." Thus, the Office proposed that "it would have been obvious to use the gel of Gross in lieu of the foam of Hermann since that it appears that either would work equally well for the common intended use."

Claim 116 is canceled and thus, obviates this rejection with regard to this claim. Applicant respectfully requests the withdrawal of this rejection.

As previously discussed, Hermann fails to disclose or suggest *the use of more than one* unique introducer catheter system, as provided by Applicants. See discussion *supra*. Instead, Hermann discloses and suggests the use of a *single catheter* introducer system 10. Hermann at Col. 2, ll. 50-52; Col. 11, ll. 21-23. Further, in the "Summary of the Invention," Hermann states that "the second aspect of the present invention [is] a method for introducing a flexible sheath to a target location in a body" *Id.* at Col. 3, ll. 20-22. Unlike Hermann, Applicants' Claims 124 and 126 provide at least for a method of reducing blood loss from a vessel and a method of repairing a vessel using at least two sheath devices, namely, a first and a second sheath device. See Applicants Amendments to the Claims *supra*. Because Herman fails to provide for all the limitations found in the claims, Gross must provide for those missing elements.

As stated by the Office, Gross teaches "a *similar* device [as to Hermann] for sealing around body-inserted instruments and uses a gel to seal around the instruments and to seal the passage completely when the instruments are removed." Office Action mailed August 12, 2003 (emphasis added). Gross, like Hermann, discloses and

suggests only a *single* thoracentesis device 10 that includes "an elongated flexible catheter 14 having a leading end 16 formed with one or more radial ports or openings 18 which allow for fluid or air communication with the body cavity to which the leading end is inserted" and its method of use. Gross at Col. 2, ll. 42-47; Col. 5, ll. 10-31. Gross' invention, however, is expressly directed to "a thoracentesis device which prevents air entry into the plural cavity and lung puncture during use." *Id.* at Col. 1, ll. 5-10. The obviousness of using a second thoracentesis device in communication with the first thoracentesis device disclosed in Gross is absent where the risk of air entering the pleural cavity and the threat of lung puncture and collapse increase significantly with the addition of a second device.

The combination of Hermann in view of Gross fails to suggest or disclose a method of use provided by Applicants' invention. Thus, Applicants' invention is patentably distinguishable over Hermann in view of Gross. Applicants respectfully request the withdrawal of this rejection.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims of the present invention define subject matter patentable over the references cited by the Examiner and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the below listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Respectfully submitted,

Date: December 10, 2003

A handwritten signature in black ink, appearing to read "J. Coulby", is written over a horizontal line.

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